JUN 2 5 2003

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda PRESTN Module, (Model family M-PRESTN) and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

June 7, 2003

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda PRESTN Module, (Model family M-PRESTN) and accessories

COMMON NAME:

Multiparameter Hemodynamic Module

CLASSIFICATION NAME:

The following Class III classifications appear applicable:

MHX	Monitor, Physiological,Patient (With Arrhythmia Detection or Alarm)	870.1025
MLD	Monitor, ST segment with Alarm	870.1025

The following Class II classifications appear applicable:

DSK	Blood pressure computer	870.1110
DRQ	Transducer signal amplifier and conditioner	870.2060
DQA	Oximeter	870.2700
DPZ	Ear Oximeter	870.2710
DRT	Cardiac Monitor (including cardiotachometer and rate alarm)	870.2300
DPS	Electrocardiograph	870.2340
DXN	Non-invasive blood pressure measurement system	870.1130
FLL	Clinical Electronic Thermometer	880.2910

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda M-PRESTN Module is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-NE12STPR Module (K993608).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda PRESTN module (model family M-PRESTN) and accessories is a hemodynamic multiparameter module which is able to measure ECG, two Invasive blood pressures, SpO2, two Temperatures, Non-invasive blood pressure and Impedance Respiration.

The intended use for the modified device is the same as the predicate, Datex-Ohmeda M-NE12STPR family module and accessories (K993608). The indications for use are also the same with the clarification for SPO2 use also during clinical motion conditions. There has been no change to the basic technology from the predicate.

The Datex-Ohmeda M-PRESTN module can be used with the following Datex-Ohmeda modular monitors which already have separate 510(k) clearances:
S/5 Anesthesia Monitor(AM), with main softwares L-ANE01(A)..00 or newer version
S/5 Compact Anesthesia Monitor (CAM), with main softwares S-00A05/06..00 rev. 10.9 or newer version, L-00A07/08..00 rev. 10.9 or newer version
S/5 Critical Care Monitor (CCM), with main softwares S-00C01/02..00 rev. 10.5 or newer version
S/5 Compact Critical Care Monitor (CCCM), with main softwares S-00C03/04..00 rev. 10.9 or newer version

There are 3 different model variants of the module:
M-PRESTN: (includes all possible parameters) NIBP, ECG, SpO2, 2*T, 2*inv. press.,Resp
M-RESTN: (does not include invasive pressures) NIBP, ECG, SpO2, 2*T, Resp
M-PRETN: (does not include SpO2) NIBP, ECG, 2*T, 2*inv. press.,Resp.
The letters in the module name stand for:
P= Invasive Pressure
R= Impedance Respiration
E= 12-Lead ECG
S= Pulse Oximetry
T= Temperature
N=NIBP, Non-Invasive Blood Pressure

For the purpose of this 510(k) "M-PRESTN" will be used to denote all models since it includes all the parameters.

The fundamental scientific technology is identical to the predicate device. However, all measurement boards and their software have been changed to allow state of the art solid state technology on all boards, including low power low voltage operation amplifier technology and new state of the art low power microcontroller technology. The boards have also been improved to fulfill the latest standard requirements including the requirements of the latest EMC standards, (IEC 60601-1-2:2001). The software has been modified accordingly to accommodate the new hardware. The front panel and its labelling has been changed because the ECG connector was made smaller.
There are new ECG cables, made for the new smaller connector. We also introduce a NIBP thigh cuff, and disposable NIBP adult cuffs as an answer to customer feedback.
There are minor changes in the customer specifications (e.g. New SpO2 calibration range: 70 to 100%) to reflect the proposed standards and customer needs.
The risk analysis has been redone to make sure none of the changes has effected the safety and effectiveness of the device.

There are minor changes in the customer specifications (e.g. New SpO2 calibration range: 70 to 100%) to reflect the proposed standards and customer needs.
The risk analysis has been redone to make sure none of the changes has effected the safety and effectiveness of the device.

Changes to the labeling include an instruction for use sheet, revised User's Manual and Brochure.

INTENDED USE as required by 807.92(a)(5)

Intended use:
The Datex-Ohmeda PRESTN module , M-PRESTN is intended to be used with Datex-Ohmeda modular monitors for monitoring hemodynamic parameters of hospitalized patients.
Indications for use:
The Datex-Ohmeda PRESTN module (model family M-PRESTN) and accessories are indicated for monitoring of hemodynamic parameters of all hospital patients. The hemodynamic parameters of the module comprise ECG (including ST-segment and arrhythmia), Impedance respiration, NIBP, Temperature, SpO2 (including monitoring during conditions of clinical patient motion), and invasive blood pressure.
Impedance Respiration measurement is indicated for patient's ages 3 and up.
The NIBP measurement is indicated for patients who weigh 5kg (11 lb.) and up.
The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda M-PRESTN Module is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-NE12STPR Module (K993608).
The redesigned M-PRESTN module has the following similarities compared to the predicate M-NE12STPR (K993608):

- identical intended use and indications for use, only clinical motion added to SpO2 measurement. Clinical motion in the M-PRESTN module uses the same algorithm as the predicate M-OSAT module (K011670).
- identical fundamental scientific technology
- use the same operating principle
- have the same safety and effectiveness
- have the same user interface and alarms
- are manufactured using the same processes

The main differences between the new M-PRESTN and the predicate M-NE12STPR (K993608) is primarily due to fact that the new M-PRESTN module has the following new parts:

- a new ECGR measurement board
- a new NIBP measurement board
- a new STP measurement board
- a new ECG patient connector

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of Datex-Ohmeda M-PRESTN Module are substantially equivalent to the predicate Datex-Ohmeda M-NE12STPR Module (K993608). For SpO2 clinical motion based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of Datex-Ohmeda M-PRESTN Module are substantially equivalent to the predicate Datex-Ohmeda M-OSAT Module (K011670).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Datex-Ohmeda PRESTN Module, (Model family M-PRESTN) and accessories complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- Performance standard for electrode lead wires and patient cables, FDA regulation 21 CFR.898.12
- ANSI/AAMI ES1-1993
- IEC60601-1:1988, Amendment 1: 1991, Amendment 2: 1995
- EN 60601-1:1990 +A1:1993 +A2:1995 +A12:1993
- UL 2601-1:1997
- CAN/CSA-C22.2 No 601.1-M90 + Supplement +S1:1994+Amdt2:1998
- IEC 60601-1-2: 2001
- IEC 60601-1-4
- IEC60601-2-27:1994 /EN60601-2-27:1994
- IEC 60601-2-30:1999 /EN 60601-2-30:2000
- IEC 60601-2-34:2000 /EN 60601-2-34:2000
- IEC 60601-2-49: 2001/ EN 60601-2-49:2001
- ISO 9919: 1994
- EN 865:1997
- AAMI EC11-1991
- AAMI EC13-2002
- AAMI EC57:1998
- AAMI SP10-1992/AAMI SP10-2002
- EN 12470-4

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda PRESTN Module, (Model family M-PRESTN) and accessories as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2003

Datex-Ohmeda
c/o Mr. Joel Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K031781
Trade Name: Datex-Ohmeda PRESTN Module, (Model family M-PRESTN) and accessoreis
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: June 8, 2003
Received: June 10, 2003

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031781

510(k) Number (if known): K031781

Device Name: Datex-Ohmeda PRESTN Module (Model family M-PRESTN) and accessories

Indications For Use:

The Datex-Ohmeda PRESTN module (model family M-PRESTN) and accessories are indicated for monitoring of hemodynamic parameters of all hospital patients. The hemodynamic parameters of the module comprise ECG including ST-segment and arrhythmia, Impedance respiration, NIBP, Temperature, SpO2 (including monitoring during conditions of clinical patient motion), and invasive blood pressure.

Impedance Respiration measurement is indicated for patients aged 3 and up.

The NIBP measurement is indicated for patients who weigh 5kg (11 lb.) and up.

The device is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031781